



# Enabling the immune system to fight cancer

Ultimovacs Company Presentation

January 18, 2023

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# Developing an off-the-shelf therapeutic cancer vaccine in a broad clinical program: UV1 shows encouraging survival results and no added toxicities

## A potential backbone therapy with checkpoint inhibitors

- target expressed in 85-90% of cancer types, multiple opportunities in solid tumors
- UV1 off-the-shelf and easy to use; providing accessibility to therapy
- Well positioned in the emerging cancer vaccine landscape



## Compelling Phase I data from malignant melanoma with pembrolizumab

- Sustained long-term overall survival; ~ 70% OS after 4 years

## Five Phase II trials ongoing; First randomized data presented at ESMO 2023

- Phase II second-line treatment of malignant mesothelioma: Clinically meaningful survival improvement, reducing risk of death by 27% (OS 15.4 vs 11.1 months)
- Phase II unresectable or metastatic malignant melanoma - readout **March, 2024**
- Phase II head and neck squamous cell carcinoma - readout **H2 2024**



# A data-driven approach across cancer indications

	Cancer indication	Checkpoint inhibitors	Patients (#)	Enrollment status	Expected topline readout	Phase I	Phase II	Sponsor	
UV1	Malignant melanoma	Ipilimumab	12	✓	✓	UV1-ipi ●		ultimovacs	
	Malignant melanoma	Pembrolizumab	30	✓	✓	UV1-103 ●		ultimovacs	
	Malignant melanoma	Ipilimumab & nivolumab	156	✓	March 2024		INITIUM ●	ultimovacs	
	Investigator-initiated trials							Contributors	
	Pleural mesothelioma	Ipilimumab & nivolumab	118	✓	✓		NIPU ●	Bristol Myers Squibb <sup>1</sup> Oslo University Hospital	
	Head and neck cancer	Pembrolizumab	75	✓	H2 2024		FOCUS ●	MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG	
	Ovarian cancer	Durvalumab & olaparib	184	Ongoing	H2 2024 <sup>2</sup>		DOVACC ●	NSGO-CTU <small>Nordic Society of Gynaecological Oncology - Clinical Trial Unit</small> AstraZeneca <sup>1</sup> ENGOT <small>European Network of Gynaecological Oncological Trial groups</small>	
	Non-small cell lung cancer (NSCLC)	Cemiplimab <sup>3</sup>	138	Ongoing	H2 2025 <sup>2</sup>		LUNGVAC ●	VESTRE VIKEN DRAMMEN HOSPITAL	
TET	Prostate cancer	Dose finding, monotherapy	12	✓	✓				

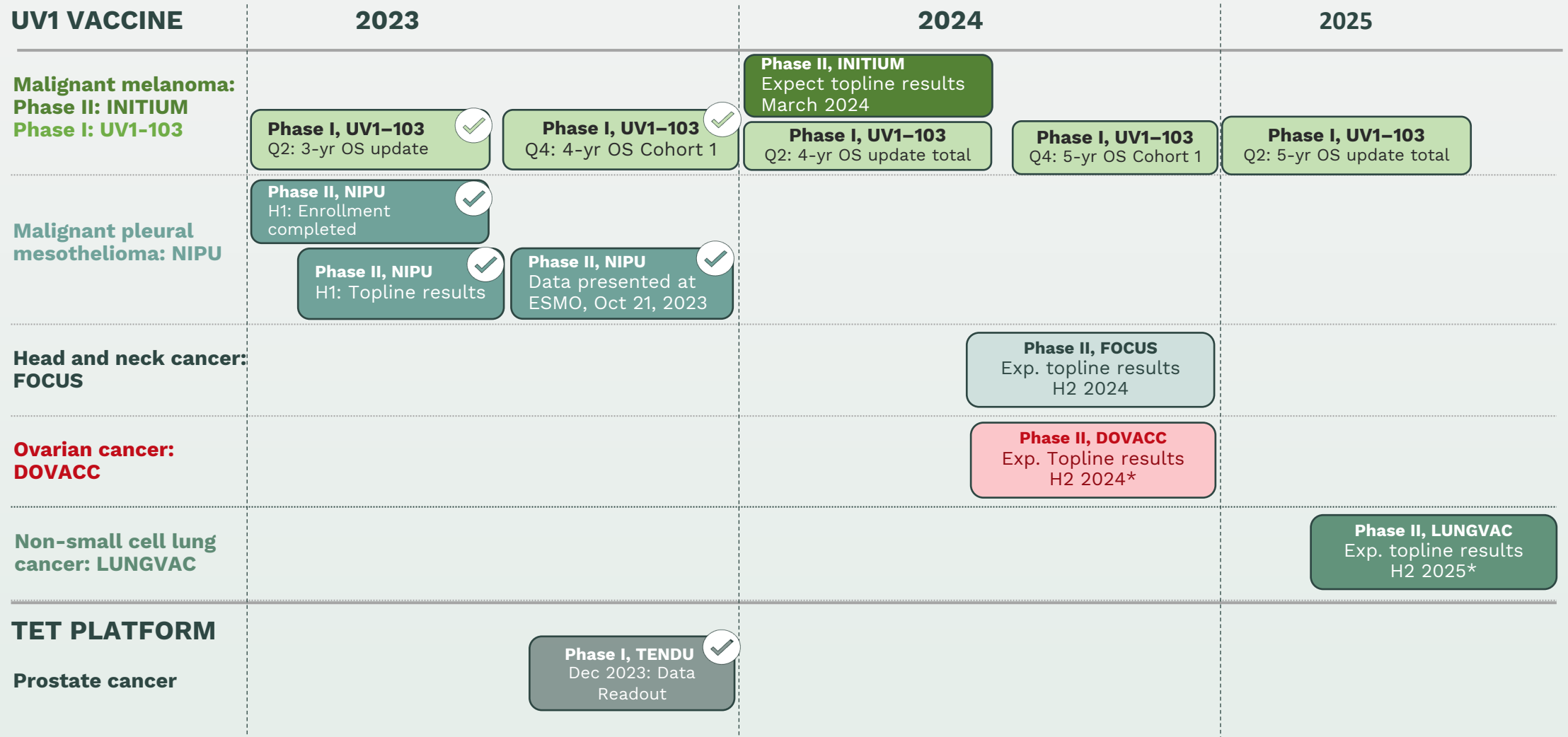


**Note:** UV1 Phase II development is further supported by good safety profile and signals of clinical efficacy observed in two other Phase I trials where 40 patients with prostate cancer and lung cancer were included. Patients in these studies have been followed for at least five years.

1: Supply agreements. 2:DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report.

3: As per 1 January 2023

# Newsflow & milestones: Key inflection points





## Contents

- 1. UV1: A universal cancer vaccine**
2. Phase I trial results
3. Phase II pipeline & program design
4. Market potential and competitive edge
5. TET platform technology
6. Key takeaways

# UV1 enhances antitumor response by activating telomerase-specific T cells

## Current CPI challenges

- Checkpoint Inhibitors (CPI) have transformed cancer therapies, but rely on a pre-existing T cell responses towards the tumor for efficacy
- Only 10-58% patients have a long-term response to CPI treatment, depending on indication<sup>1</sup>
- A universal cancer vaccine could address these challenges and improve the immune response

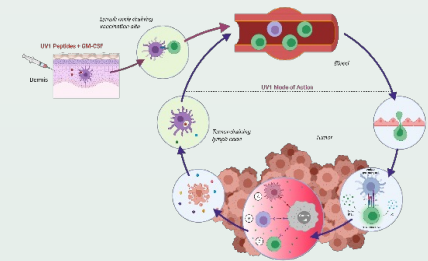
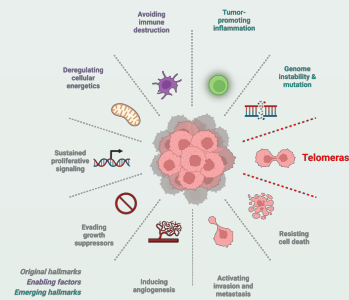
## Approach Ultimovacs

### 1 Telomerase

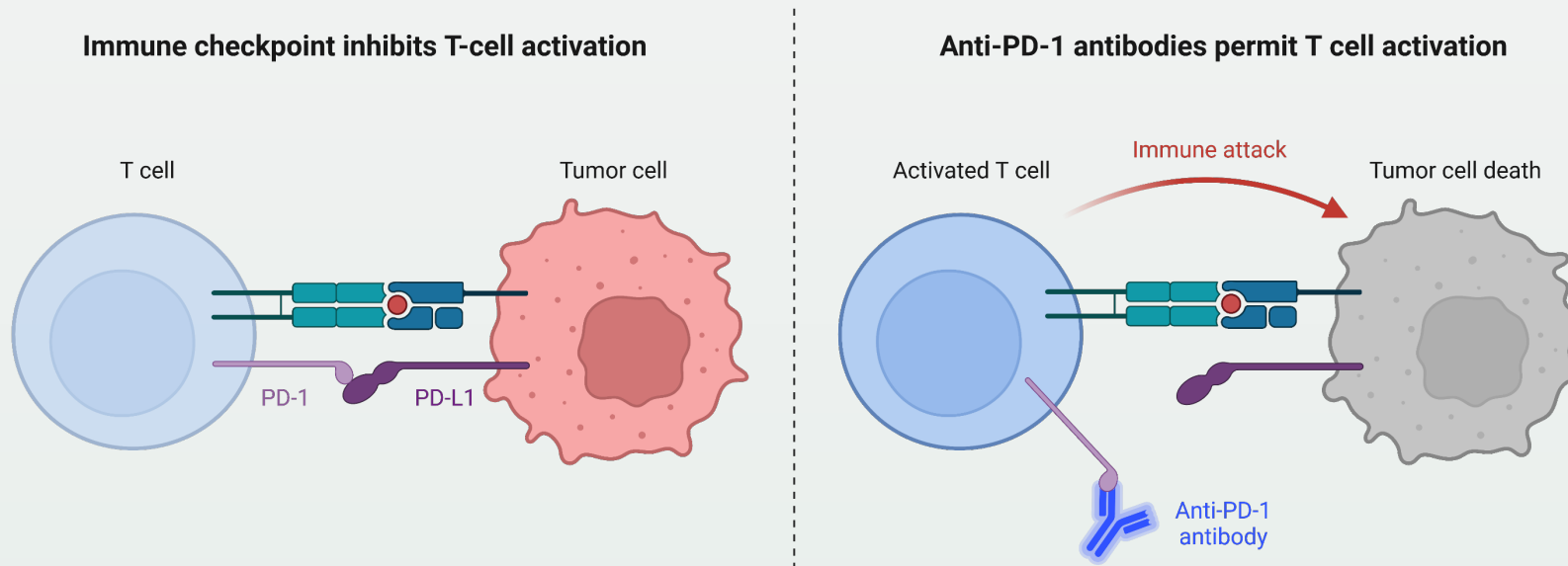
- Lead candidate UV1 targets telomerase (TERT), which plays an essential role in tumor proliferation and immortality
- Telomerase is universally expressed by cancer cells (85-90%) and present throughout all tumor stages
- No safety signals seen from healthy tissues expressing telomerase (e.g. stem cells)

### 2 Mechanism of action

- Telomerase peptides are picked up by antigen-presenting cells and prime T cells
- Telomerase-specific T cells migrate to the tumor site and initiate tumor killing
- Through cytokine secretion, the T cells activate other immune cells, enhancing the immune response against the tumor



# CPIs have transformed cancer therapy, but efficacy can be improved

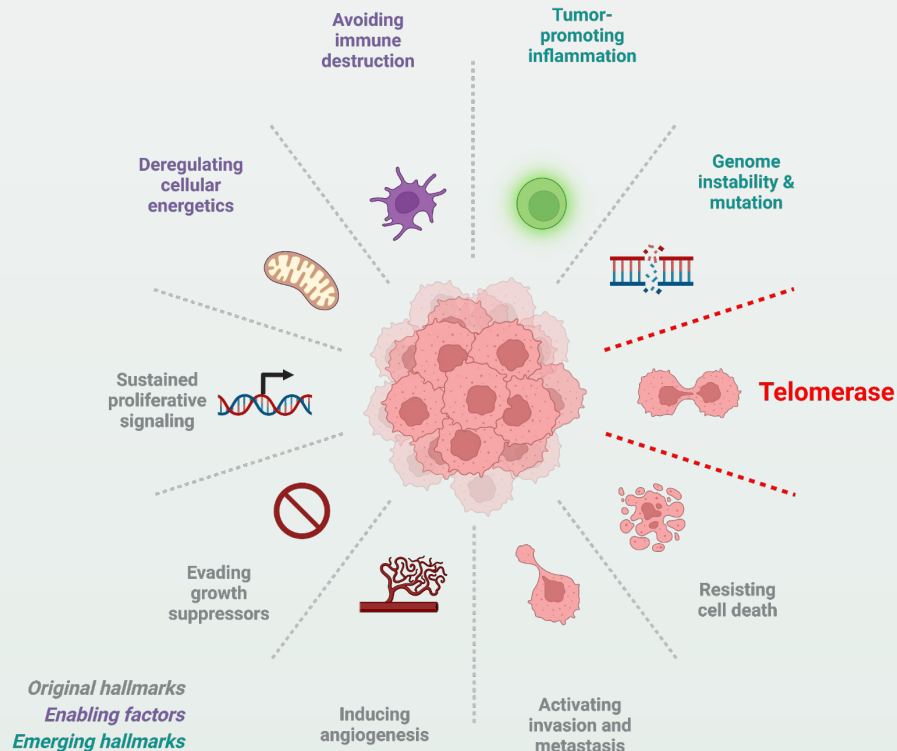


- CPIs rely on **spontaneous** T cell responses against tumors, which remain the biggest bottleneck for broader CPI efficacy<sup>1</sup>
- Most patients do not experience clinical benefit from checkpoint inhibition due to large variability in spontaneous anti-tumor immune responses
- **UV1 is ideally positioned to improve the T cell response** required for broader efficacy



# UV1 induces T cell responses against telomerase – a “hallmark of cancer” present in 85-90% of the different tumor types

## Hallmarks of Cancer<sup>1</sup>



### Telomerase Characteristics

### UV1 Vaccine Qualities

#### Universal

85-90% of tumor types express telomerase<sup>2,3</sup>

Applicable to a broad range of cancer types

#### Essential

Tumor cells depend on expressing telomerase

High relevance in heterogenous tumor environments

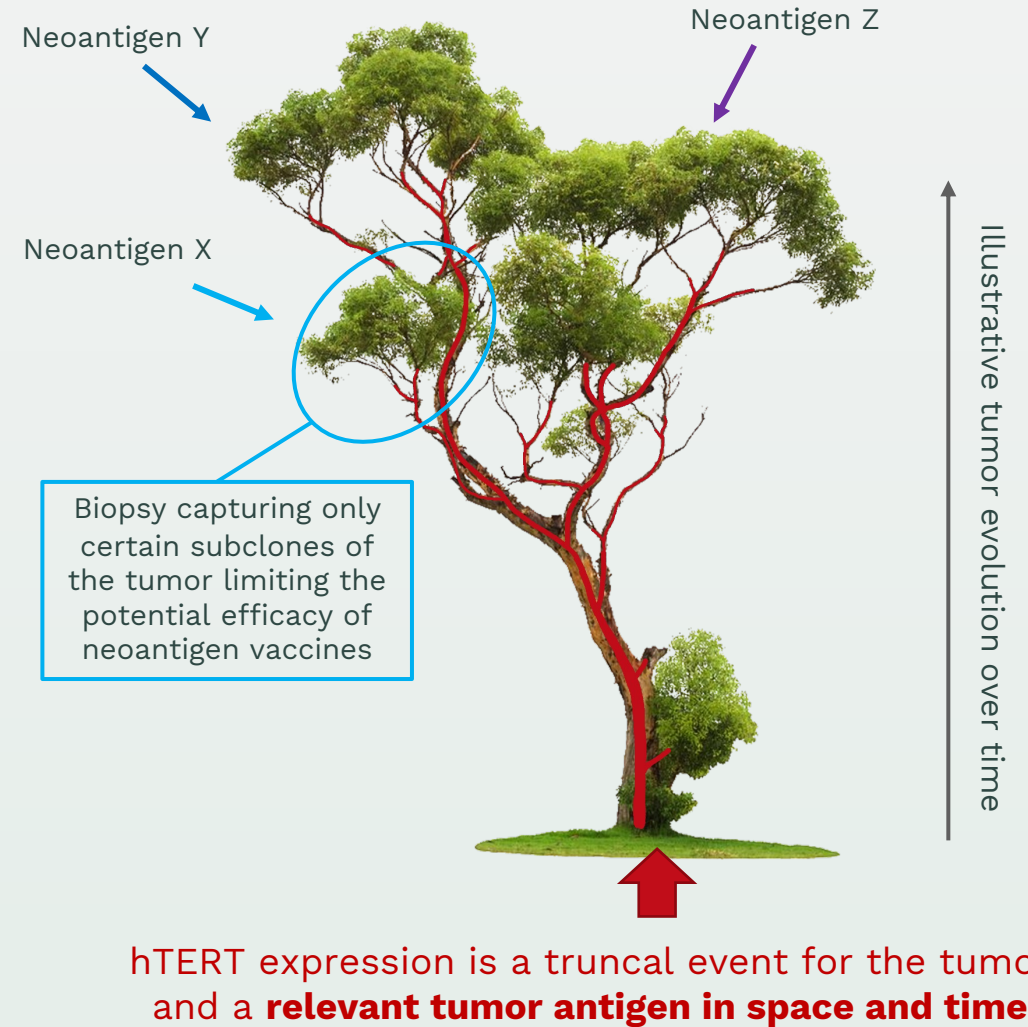
#### Enduring

Present throughout tumor evolution: primary to metastatic cancer

Enduring and relevant immune response over time

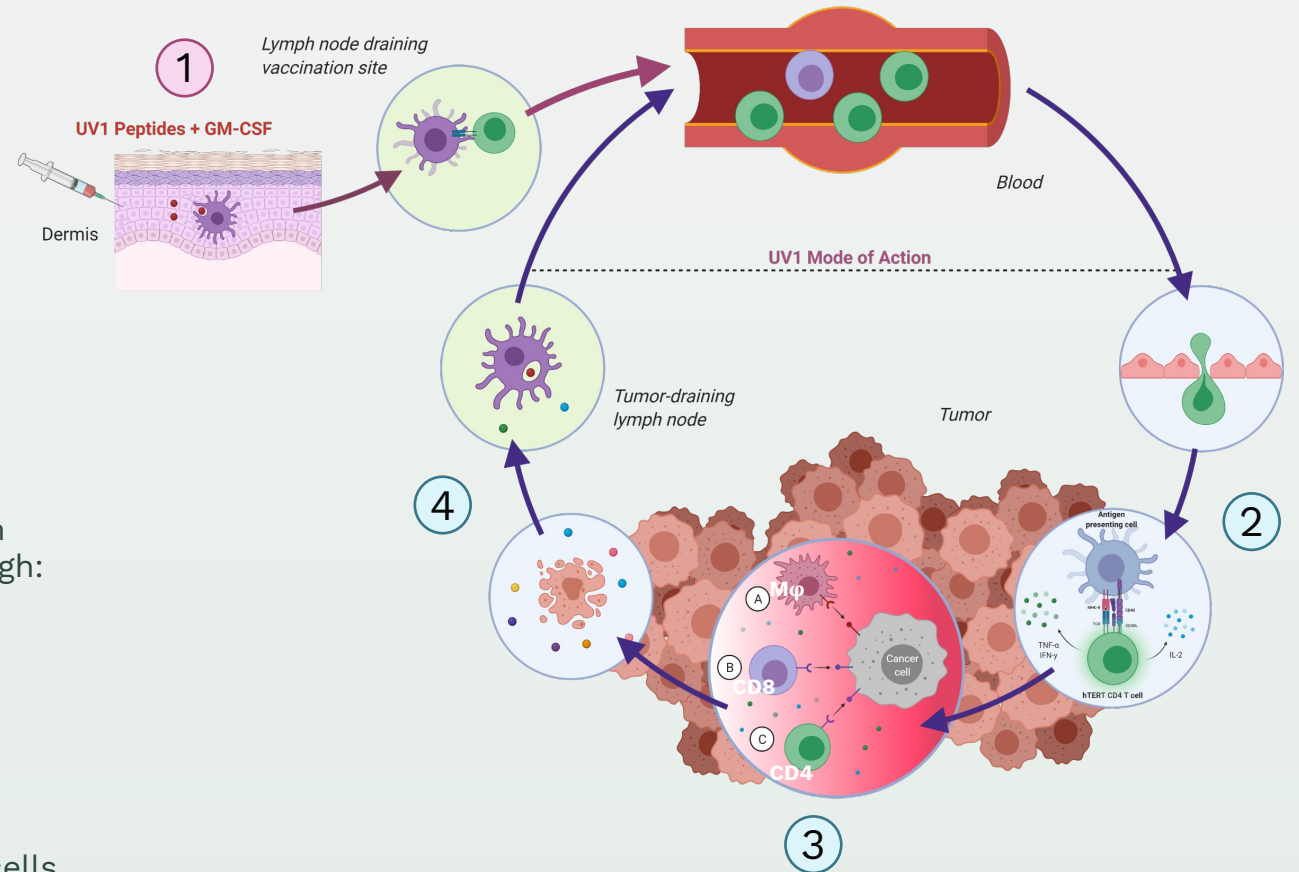
# UV1 activates hTERT specific CD4-helper T lymphocytes

- **Mechanism of action:** Vaccination induces T cell responses, which have pro-inflammatory functions and roles in activation of CTLs and memory T cell formation
- **Vaccine design:** UV1 consists of three synthetic long peptides (one 30-mer, two 15-mers), covering the catalytic site of human telomerase reverse transcriptase – hTERT
- **Easy to use:** Peptides are promiscuous with respect to HLA class I and II alleles – No need for pre-screening of HLA type or other biomarkers
- **Administration:** 8 UV1 intradermal vaccinations over a 14-week period – off the shelf. Local administration of GM-CSF as vaccine adjuvant to attract DCs
- **Safe:** UV1 does not inhibit telomerase activity but generates T cell responses recognizing fragments of telomerase presented in the context of HLA molecules on cells in the tumor. No safety signals seen from healthy tissues expressing telomerase (e.g. stem cells).
- **More than 300 cancer patients have received treatment with UV1 in clinical trials. To date, no safety concerns have been reported.**



# UV1 mode of action and downstream mechanisms enhance tumor killing

- 1 **Intradermal injection of UV1 and activation of TERT-specific T cells**
- 2 **Improved priming of anti-tumor immune responses**
  - T cells bind their antigen (TERT) expressed on local APCs and the T cells release cytokines (TNF- $\alpha$ , IFN- $\gamma$  and IL-2) inducing a pro-inflammatory “hot” tumor microenvironment
- 3 **Enhanced intratumoral activation of T cells**
  - T cells activate other cells of the immune system through cytokine secretion, directing killing through:
    - i. Macrophages
    - ii. CD8 T cells
    - iii. CD4 T cells
- 4 **Increased tumor cell killing**
  - Dying tumor cells release antigens
  - These are taken up by APCs and presented to T cells, broadening the immune response against the tumor










## Contents

1. UV1: A universal cancer vaccine
- 2. Phase II pipeline & program design**
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# UV1 clinical program consists of five comparative, randomized Phase II trials in different cancer types and CPI combinations

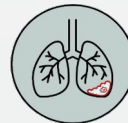
Trial design	 <b>1 NIPU</b>	 <b>2 INITIUM</b>	 <b>3 FOCUS</b>	 <b>4 DOVACC</b>	 <b>5 LUNGVAC</b>
<b>CPI combination</b>	Ipilimumab + nivolumab	Ipilimumab + nivolumab	Pembrolizumab	Durvalumab + olaparib	Cemiplimab
<b>Indication</b>	Second line mesothelioma	First line malignant melanoma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
<b>Timeline</b>	2020 – 2023	2020 – 2023	2021 – 2023	2021 – 2023	2022 – 2024
<b>Expected topline results</b>	<b>Announced October 2023</b>	<b>March 2024</b>	<b>H2 2024</b>	H2 2024 <sup>1</sup>	H2 2025 <sup>1</sup>
<b>No. of patients</b>	N=118	N=156	N=75	N=184	N=138
<b>Enrollment status<sup>2</sup></b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>25% recruited</b>	<b>~ 10% recruited</b>
<b>Sites &amp; countries</b>	6 sites in NO, SE, DK, ES, AU,	40 sites in US, NO, BE, UK	10 sites in DE	>40 sites in NO, SE, DK, FI, BE, NL, DE, AT, LT, EE, GR	8-10 sites in NO

**Primary endpoint: Progression Free Survival (PFS)**

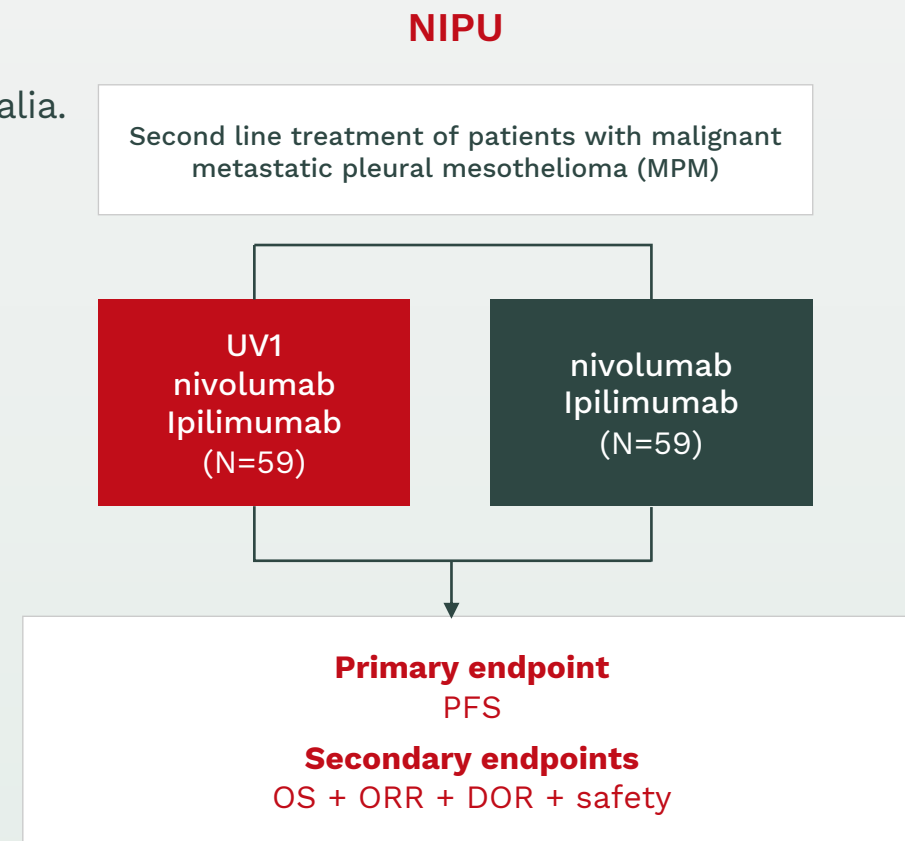
**Secondary endpoints: Overall Survival (OS) + Objective Response Rate (ORR) + Duration of Response (DOR) + safety**

# NIPU randomized Phase II trial design

## Second-line malignant metastatic pleural mesothelioma (MPM)

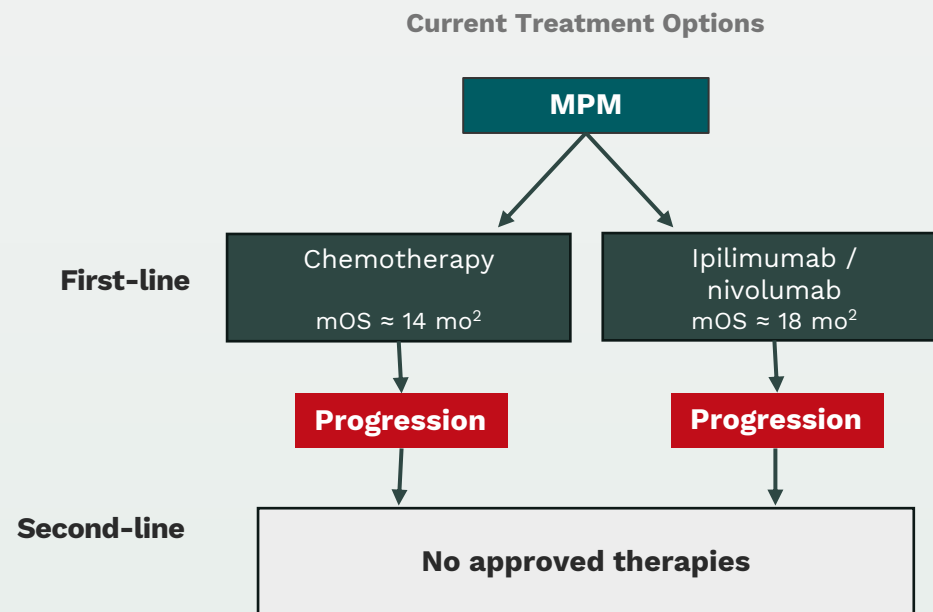


- **Combination:** nivolumab, ipilimumab
- **Contributors:** Oslo University Hospital (sponsor), BMS
- **Hospitals:** 118 from six sites in Norway, Sweden, Denmark, Spain and Australia.
  - FPI June 2020, LPI January 2023
- **Eligible patients:**
  - Inoperable malignant pleural mesothelioma
  - Age  $\geq$  18 yrs
  - ECOG Status 0-1
  - Measurable disease according to modified RECIST
  - Adequate organ function
  - Previously treated with first-line chemotherapy
- **Primary Endpoint**
  - Progression-free survival (PFS) per Blinded Independent Central Review (BICR)
  - Target HR 0.6, Power 80%, 1-sided alpha 0.1
  - Event-driven design: Read-out when 69 PFS events occurs
- **Secondary Endpoints**
  - Overall survival (OS)
  - Objective response rate (ORR, per BICR)
  - Safety



# MPM is one of the most challenging cancers to treat

- Most patients:
  - Are diagnosed with advanced disease
  - Have poor prognosis and few therapeutic options
  - Don't have surgery as an option
- Chemotherapy has been the Standard of Care (SoC) for the past 20 years
- Ipilimumab and nivolumab (IPI-NIVO) was approved in 1st line treatment by regulatory authorities in 2020/2021<sup>1</sup>
- Despite current improvement in SoC, patients with MPM remain an underserved population with a high unmet medical need



# NIPU baseline demographics

**OPDIVO + YERVOY**  
(nivolumab) (ipilimumab)  
**UV1 vaccine**

**OPDIVO + YERVOY**  
(nivolumab) (ipilimumab)

		<b>UV1 plus IPI-NIVO (n=59)</b>	<b>IPI-NIVO (n=59)</b>	<b>Total (N=118)</b>
<b>Sex – n (%)</b>	Female	14 (23.7)	12 (20.3)	26 (22.0)
	Male	45 (76.3)	47 (79.7)	92 (78.0)
<b>Age</b>	Median	71	72	71
	Range	39-79	42-83	39-83
<b>ECOG – n (%)</b>	0	17 (28.8)	18 (30.5)	35 (29.7)
	1	42 (71.2)	41 (69.5)	83 (70.3)
<b>Histology – n (%)</b>	Epithelioid	44 (74.6)	47 (79.7)	91 (77.1)
	Sarcomatoid	5 (8.5)	4 (6.8)	9 (7.6)
	Biphasic	5 (8.5)	7 (11.9)	12 (10.2)
	Rhabdoid	1 (1.7)	0 (0)	1 (0.8)
	Unknown	4 (6.8)	1 (1.7)	5 (4.2)
<b>PD-L1 – n (%)</b>	<1	31 (52.5)	32 (54.2)	63 (53.4)
	1-49	6 (10.2)	4 (6.8)	10 (8.5)
	≥50	2 (3.4)	4 (6.8)	6 (5.1)
	Unknown	20 (33.9)	19 (32.2)	39 (33.1)



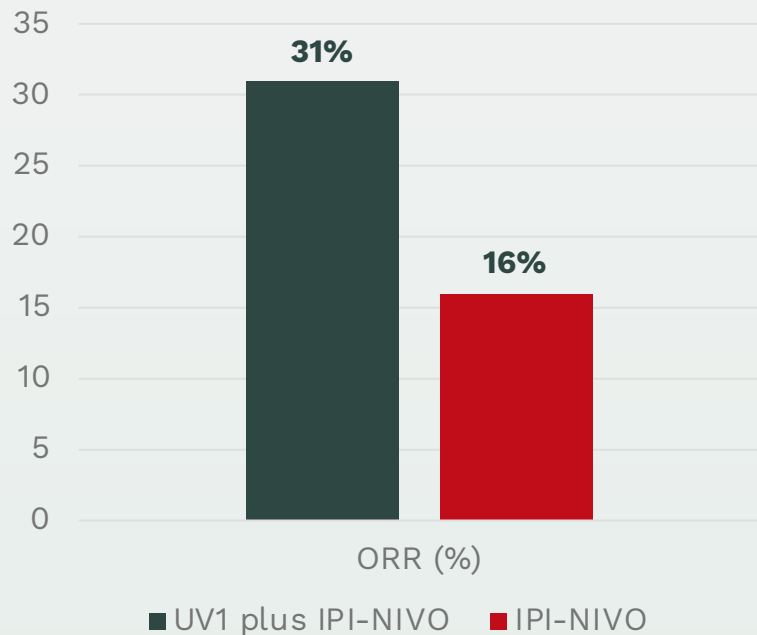
## UV1 Maintains an Excellent Safety Profile in the NIPU study

**The addition of UV1 to IPI-NIVO was safe and did not noticeably increase occurrences of serious adverse events**

- In the NIPU trial, the percentage of patients with serious adverse events was similar in both arms
  - UV1 plus IPI-NIVO: 36 patients (61.0%)
  - IPI-NIVO: 35 patients (59.3%)

# Near doubling of ORR and clinically meaningful prolonged survival

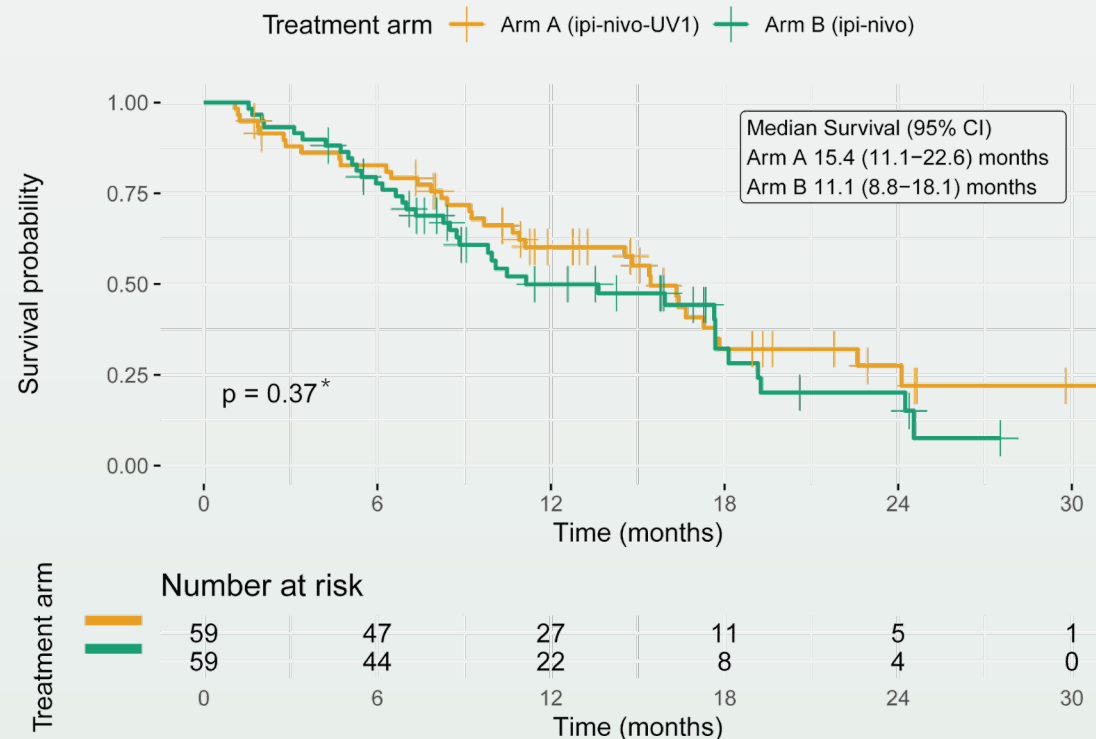
**Objective Response Rates (per BICR)**



**Objective Response Rate (per BICR)**

Arm A (UV1 plus IPI-NIVO): 31%  
 Arm B (IPI-NIVO): 16%  
 Odds Ratio 2.44 (80% CI, 1.35-4.49, 1-sided p value = 0.028)

**Overall Survival**

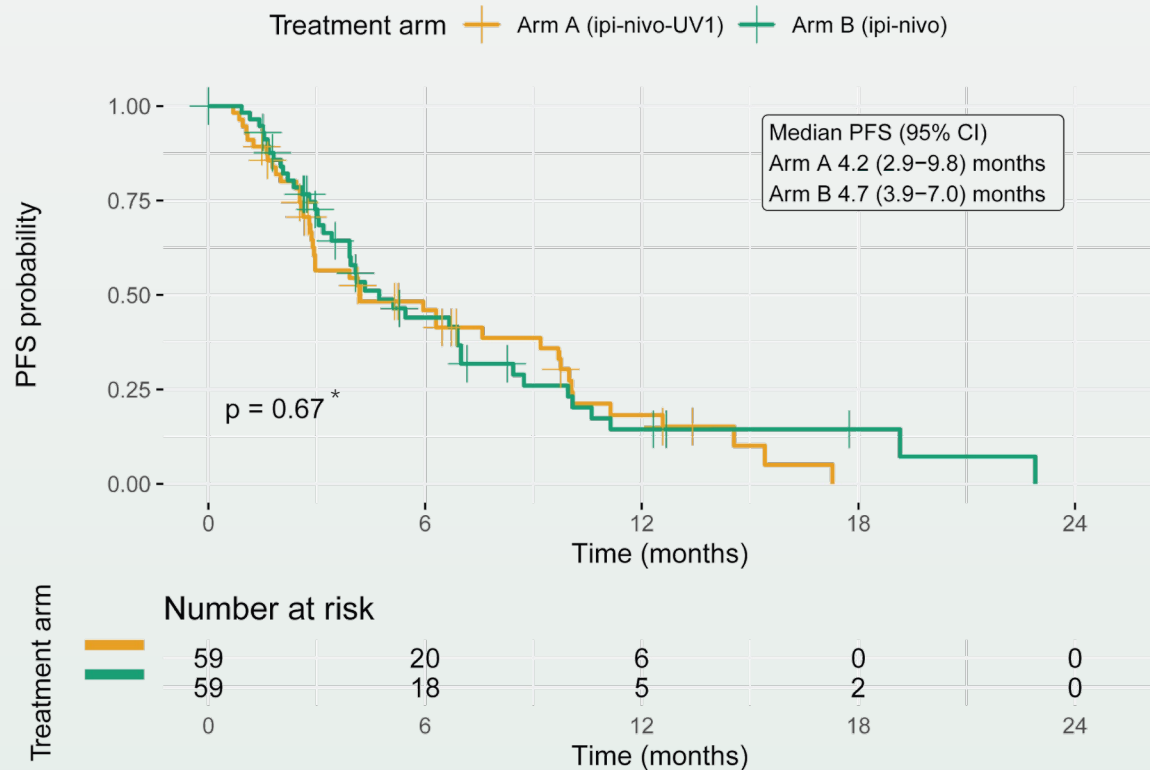


**Overall Survival†**

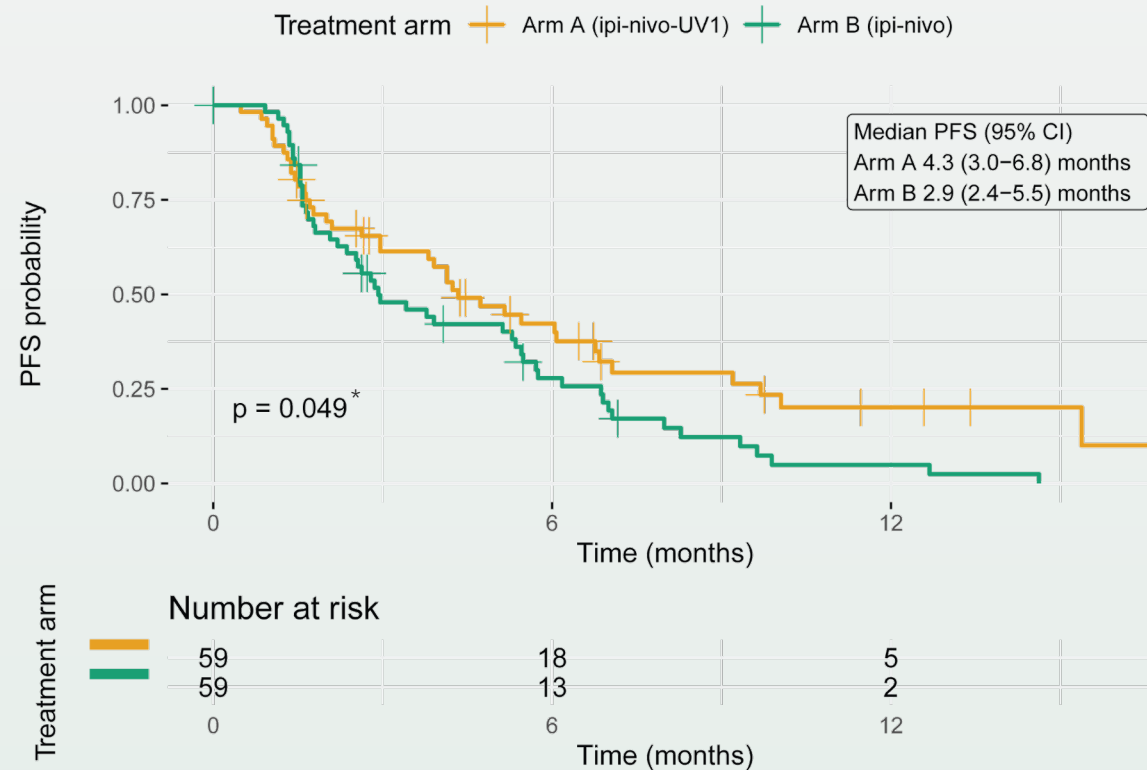
UV1 plus IPI-NIVO improved overall survival (OS), reducing the risk of death by 27% (HR=0.73 [80% CI, 0.53-1.00], 1-sided p value = 0.0985), with a median OS of 15.4 months (95% CI, 11.1-22.6) versus 11.1 months (95% CI, 8.8-18.1) for IPI-NIVO alone.

# Progression-free survival (PFS) reported by BICR and Investigator Assessment

**Blinded Independent Central Review (BICR)**



**Investigator Assessment**



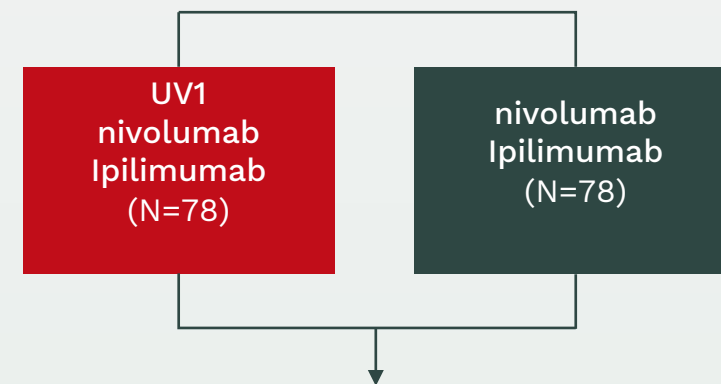
**Progression-free survival based on BICR<sup>†</sup>**  
 HR = 1.01 (80% CI 0.75–1.36, 1-sided p value = 0.4895)

**Progression-free survival based on Investigator Assessment**  
 HR = 0.60 (80% CI 0.45–0.81, 1-sided p value = 0.0125)

# INITIUM – unresectable or metastatic malignant melanoma



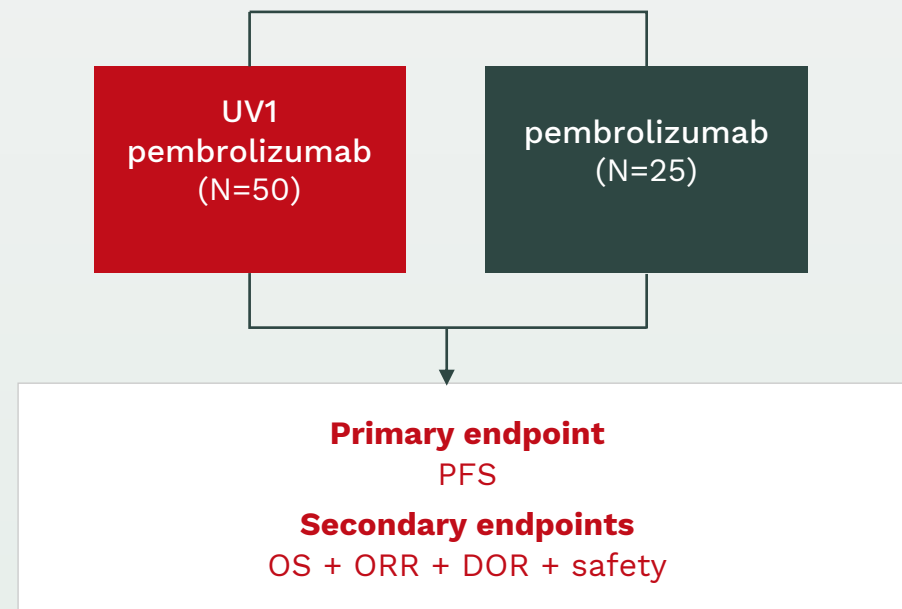
- Sponsored by Ultimovacs
- Enrolled 156 patients from 39 sites in four countries: US, UK, Belgium and Norway.
- First patient enrolled June 2020, last patient enrolled in July 2022
- **Topline results expected in March 2024** after the last patient has been followed for 18 months. 70 events have not occurred.
- Supplementary single-arm study completed
  - Enrollment of 21 patients, treated with UV1 + ipi/nivo
  - Not included in topline results from INITIUM
  - Results will provide in-depth data on biological activity and mode of action of the vaccine induced T cells



# FOCUS - metastatic or recurrent head and neck squamous cell carcinoma



- Investigator-initiated trial sponsored by Halle University Hospital network, supported by Ultimovacs
- Enrolled 75 patients from ten sites in Germany
- First patient enrolled August 2021, last patient enrolled in August 2023
- FOCUS is a landmark study: The data will be analyzed 12 months after enrollment of the last patient
- **Topline results expected H2 2024**, and will include readout of all endpoints up to 12 months and the primary endpoint PFS at 6 months

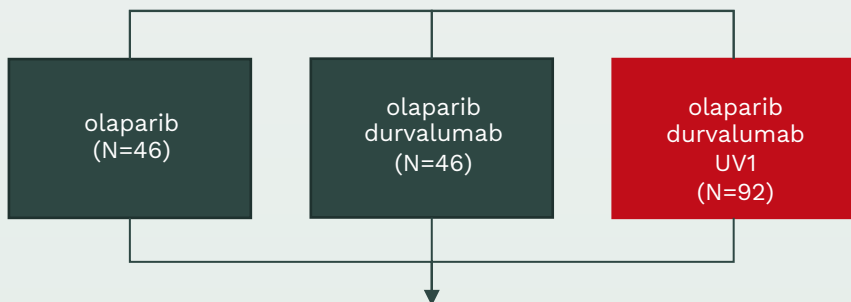


# DOVACC and LUNGVAC UV1 Phase II Trials

## DOVACC: High-grade BRCA negative ovarian cancer, second line maintenance



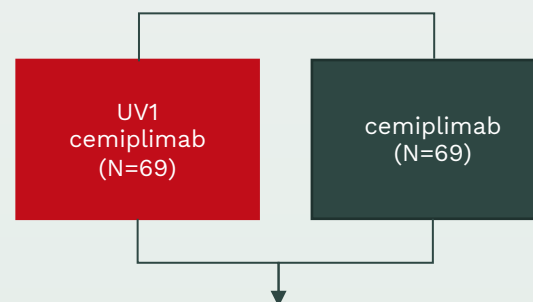
- **Combination:** olaparib, durvalumab
- **Contributors:** NSGO/ENGOT (sponsor), AstraZeneca
- **Patients:** 184 from more than 40 sites in more than 10 European countries
- **Recruitment:** 25%
- First patient enrolled December 2021
- 46 patients enrolled as of November 7, 2023 (Q3 2023 reporting)
- **Milestones:** Topline results expected H2 2024 (to be updated in Q4 reporting)



## LUNGVAC: Advanced or metastatic non-small cell lung cancer (NSCLC)



- **Combination:** cemiplimab
- **Contributors:** Sponsored by Drammen Hospital
- **Patients:** 138 patients from 8-10 hospitals in Norway
- **Recruitment:** ~10%
- First patient enrolled October 2022
- 13 patients\* enrolled as of November 7, 2023 (Q3 2023 reporting)
- **Milestones:** Topline results expected H2 2025 (to be updated in Q4 reporting)



**Primary endpoint: PFS**

**Secondary endpoints: OS + ORR + DOR + safety**



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# Strong Phase I efficacy and safety data of UV1 in two combination trials

## Malignant melanoma

Trial design	① UV1 + ipilimumab	② UV1 + pembrolizumab
<b>Nr. of patients</b>	12	30 (cohort 1: 20, cohort 2: 10)
<b>UV1 dose</b>	300 µg	300 µg
<b>GM-CSF dose</b>	75 µg	Cohort 1: 37.5 µg, cohort 2: 75 µg
<b>Primary endpoint</b>	Safety (good)	Safety (good)
<b>Secondary endpoints</b>	PFS, OS, ORR, exploratory biomarkers	PFS, OS, ORR, exploratory biomarkers
<b>Clinical activity</b>	Strong signals	Strong signals
<b>Publication</b>	Poster presentation at <a href="#">SITC Annual Meeting 2021</a> , publication in <a href="#">Frontiers in Immunology</a> (May 2021)	Data reported at ASCO 2021 and updates at the Conference of the Society for Melanoma Research 2022, publication in <a href="#">Clinical Cancer Research</a> (2023)

### FDA designations

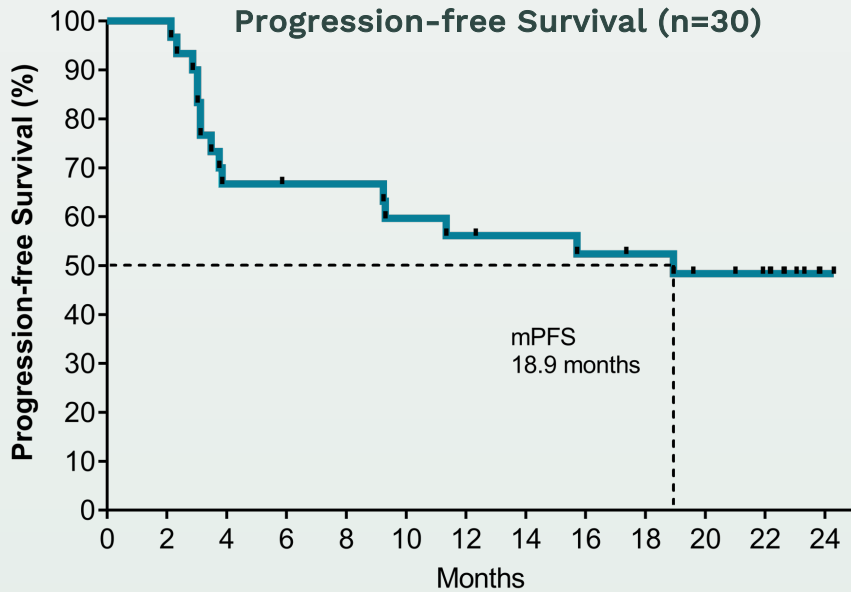
- In Oct 2023, UV1 was granted **Orphan Drug Designation** from FDA for treatment of mesothelioma
- In Dec 2021, UV1 was granted **Orphan Drug designation** from FDA for treatment of stage IIB-IV melanoma
- In Oct 2021, **Fast Track designation** was granted for UV1 as add-on therapy to ipilimumab or pembrolizumab for treatment of unresectable or metastatic melanoma



# Sustained long-term overall survival in Phase I trial UV1-103 in malignant melanoma patients treated with pembrolizumab and UV1 vaccination

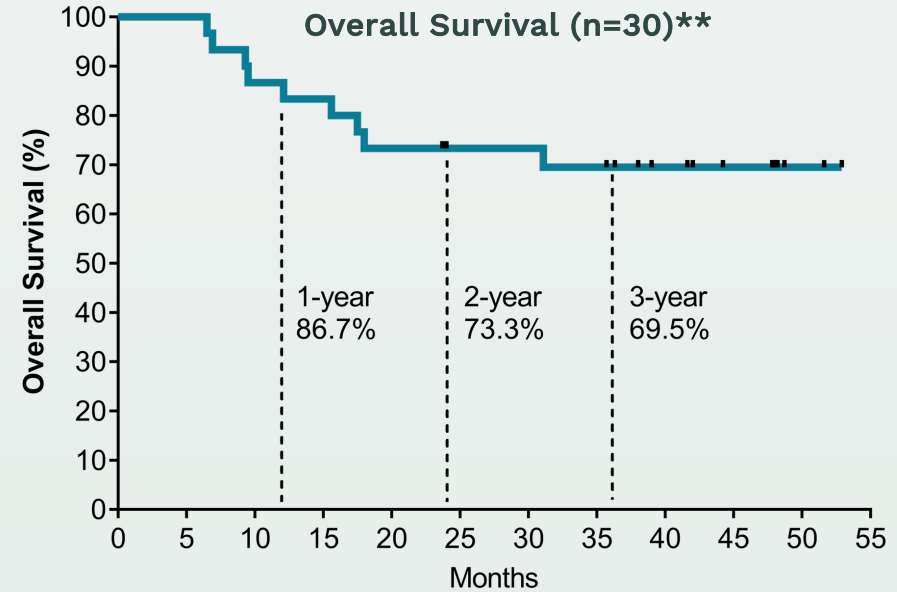
## Median progression free survival:

- Cohort 1+2 combined is 18.9 months



## Overall survival:

- Cohort 1+2 combined after 12 months: 86.7%
- Cohort 1+2 combined after 24 months: 73.3%
- Cohort 1+2 combined after 36 months: 69.5%
- Cohort 1 after 48 months: 73.8%\*

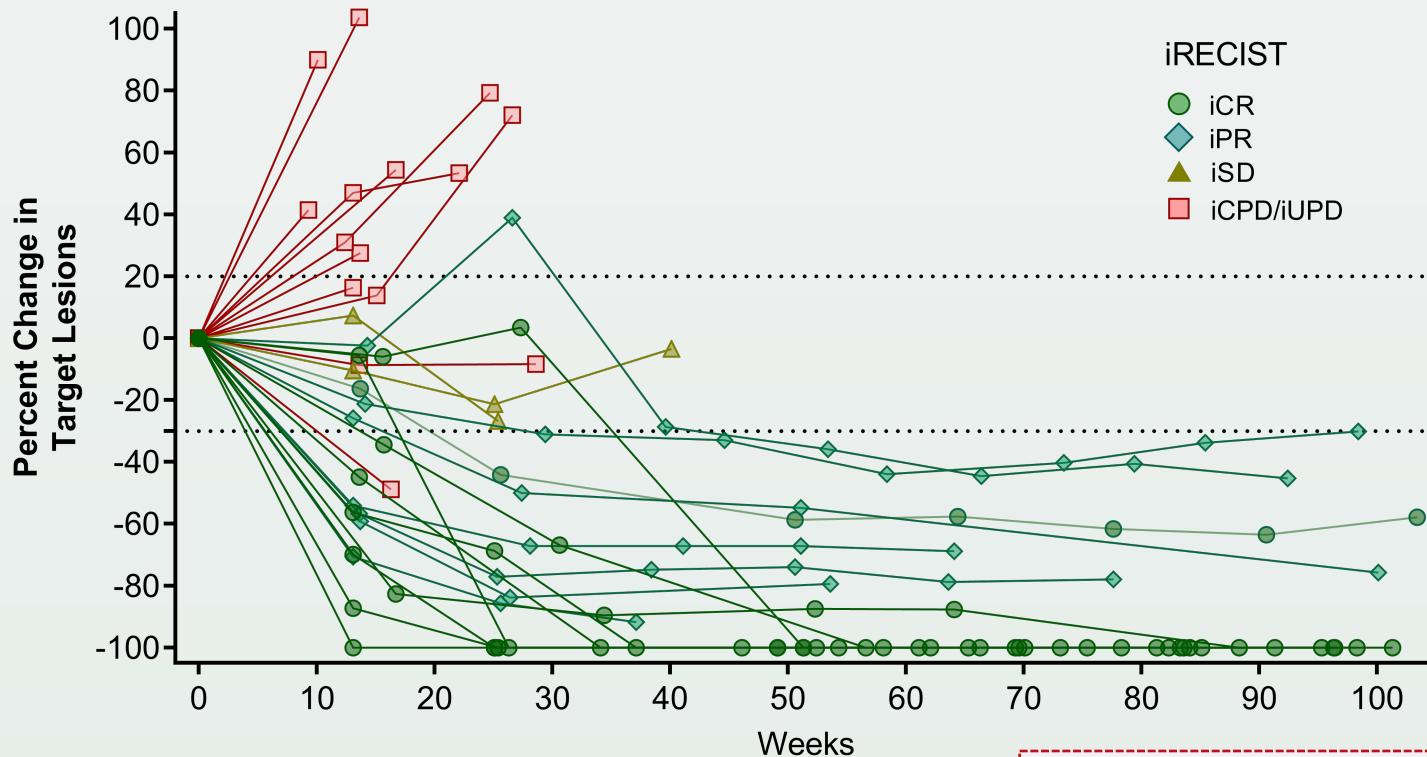


- **UV1 has demonstrated a good safety profile; no unexpected safety issues have been observed in the trial**
- **Patients will continue to be followed for long-term survival**

# Robust clinical responses in patients typically obtaining reduced CPI efficacy

Sustained high ORR and CR rate to UV1 + pembrolizumab combo in PD-L1 negative tumors

Responses lasting up to 2 years (maximum follow-up)



Best Overall Response (iRECIST)	n	%
<b>ORR (n=30)</b>	17	56.7
Complete Response	10	33.3
Partial Response	7	23.3
Stable Disease	2	6.7
Progressive Disease	11	36.7
<b>ORR in PD-L1 negative patients (n=14)*</b>	8	57.1
Complete Response	5	35.7
Partial Response	3	21.4

Historical reference study: KEYNOTE-006 (FDA Package insert; Robert C, 2019; Carlino MS, 2018)

<b>ORR:</b> 34-42%	<b>ORR PD-L1 neg:</b> 24.3% (95% CI, 16.4%–33.7%)
<b>CR:</b> 5-14%	<b>CR PD-L1 neg:</b> 5.8%



Each line represent one patient, color- and symbol-coded according to best objective response achieved per iRECIST  
 Each symbol represents a CT measurement of the tumor size relative to baseline  
 • PD-L1 staining with 22C3 pharmDx for Autostainer Link 48. PD-L1 positive defined as ≥1% of tumor cells



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# UV1 is poised to tap into a large market due to its combination with CPIs - strong competitive edge in the emerging cancer vaccine landscape

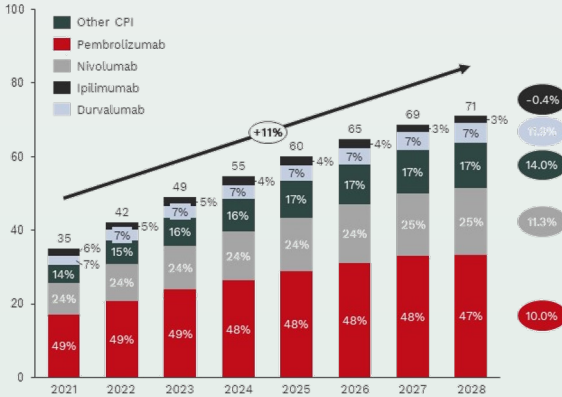
## 1 Combination with CPIs

- UV1 can be combined with the (standard-of-care) CPI in a broad range of cancer types
- Use of UV1 as an add-on therapy is currently evaluated in 5 different cancer indications
- Large opportunity to expand to other cancer types

Cancer Indication	[New] adjuvant	UV1	Keytruda	Opdivo	Ultibro	Jemperli	Imfinzi	Tecentriq	Rochevici	Yervey	Injelo	Opdivog
		IPD1	perforanzumab	ipilimumab	cemiplimab	dostarlimab	binutumab	atezolizumab	avelumab	enfortumab	trenezumab	relatlimab
Malignant melanoma	✓	with Tenryo								with Opdivo		with Tenryo
Lung (NSCLC/PLD)	✓	with Tenryo								with Opdivo		with Tenryo
HNSCC	✓	with Tenryo								with Opdivo		with Tenryo
Neuroblastoma	✓	with Tenryo								with Opdivo		with Tenryo
Ovarian	✓	with Tenryo								with Opdivo		with Tenryo
Prostate	✓	with Tenryo								with Opdivo		with Tenryo
Bladder	✓	with Tenryo								with Opdivo		with Tenryo
Urothelial/Bladder	✓	with Tenryo								with Opdivo		with Tenryo
MSI-High	✓	with Tenryo								with Opdivo		with Tenryo
Gastric	✓	with Tenryo								with Opdivo		with Tenryo
Cervical	✓	with Tenryo								with Opdivo		with Tenryo
Uterine	✓	with Tenryo								with Opdivo		with Tenryo
Mucosal and	✓	with Tenryo								with Opdivo		with Tenryo
Head&Neck	✓	with Tenryo								with Opdivo		with Tenryo
Breast	✓	with Tenryo								with Opdivo		with Tenryo
Pancreatic	✓	with Tenryo								with Opdivo		with Tenryo
Esophageal	✓	with Tenryo								with Opdivo		with Tenryo
Endometrial	✓	with Tenryo								with Opdivo		with Tenryo
Osteo	✓	with Tenryo								with Opdivo		with Tenryo

## 2 Substantial market potential

- The target population and market potential is large and growing: the US CPI market is expected to grow by 15% p.a. until 2028
- CPIs most relevant to UV1 currently represent appr. 85% of the market



## 3 Competitive edge

- UV1 is well positioned in the overall cancer vaccine landscape
- Competitive advantages are related to ease of use, low-cost production, and simple logistics, enabling broad patient access to therapy



# Multiple combination opportunities with checkpoint inhibitors - broad potential for UV1 as backbone therapy



Cancer indication	(Neo-) adjuvant	UV1	Keytruda	Opdivo	Libtayo	Jemperli	Imfinzi	Tecentriq	Bavencio	Yervoy	Imjudo	Opdualag
			pembrolizumab	nivolumab	cemiplimab	dostarlimab	durvalumab	atezolizumab	avelumab	ipilimumab	tremelimumab	relatlimab
			PD1				PD-L1			CTLA-4		LAG3
Malignant melanoma		✓		with Yervoy						with Opdivo		with Yervoy
Lung (NSCLC/SCLC)		✓		with Yervoy			with Imjudo			with Opdivo	with Imfinzi	
HNSCC		✓		with Yervoy						with Opdivo		
Mesothelioma		✓		with Yervoy						with Opdivo		
Ovarian		✓										
Prostate		✓										
Renal				with Yervoy						with Opdivo		
Urothelia/Bladder				with Yervoy						with Opdivo		
MSI-high				with Yervoy						with Opdivo		
Gastric				with Yervoy						with Opdivo		
Cervical				with Yervoy						with Opdivo		
Liver				with Yervoy			with Imjudo			with Opdivo	with Imfinzi	
Merkel cell												
Hodgin Lymphoma				with Yervoy						with Opdivo		
Breast												
Pancreatic												
Esophageal				with Yervoy						with Opdivo		
Endometrial												
Colon				with Yervoy						with Opdivo		

Note: The number of indications included in the table is limited. CPI product approval may include additional indications.

Checkpoint inhibitor approved indication
  UV1 clinical trials

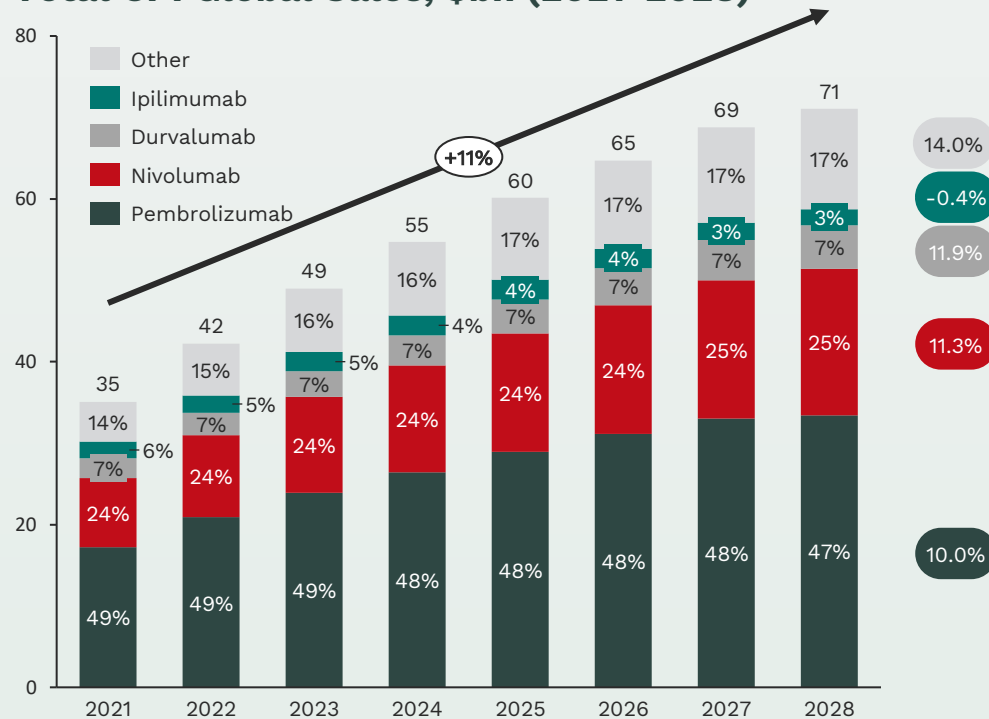


Source: Global Data, 2023, Product package inserts Q2 2023, Company websites  
 Incyte's PD-1 program (Zynys) approved for Merkel cell carcinoma (US) not included. CPI program approved in China not included.

# UV1 is uniquely positioned with Phase II trials in combination with 5 out of the top 6 checkpoint inhibitors

- UV1 is to be **combined with CPI therapy** to improve treatment outcomes: currently around one third of cancer patients is **eligible to receive CPI<sup>1</sup>**
- UV1 is under investigation with **5 out of the top 6 CPIs**, which together account for **~85% of the CPI market**

**Total CPI Global Sales, \$bn (2021-2028)**



Marketed CPIs	UV1 trial	Indication
1. Pembrolizumab (Keytruda®)	FOCUS	Head & neck cancer
2. Nivolumab (Opdivo®)	INITIUM, NIPU	Malignant melanoma, mesothelioma
3. Atezolizumab (Tecentriq®)		
4. Ipilimumab (Yervoy®)	INITIUM, NIPU	Malignant melanoma, mesothelioma
5. Durvalumab (Imfinzi®)	DOVACC	Ovarian cancer
6. Cemiplimab (Libtayo®)	LUNGVAC	Non-small cell lung cancer

# The UV1 vaccine is off-the-shelf and easy-to-use, with low production costs and simple logistics, enabling broader patient access to therapy

## 1 Easy to use

- UV1 is an **off-the-shelf** product, i.e. can be administered locally, facilitating broad access
- 8 **intra**dermal injections, no complex infrastructure required
- **No need for pre-screening** of HLA type or other biomarkers. UV1 peptides are functional with both HLA class I and II alleles: it can be used in the general population



## 2 Low-cost production

- **Low manufacturing cost**
- Straight forward manufacturing process by **standard peptide synthesis**
- **Commercial scale manufacturing process established** with well-renowned CMOs



## 3 Simple logistics

- Stable product with **3 years shelf life** at 5°C
- Standard shipping and **simple on-site preparation**, i.e., reconstitution with water
- **Low handling costs** (manpower)
- Does not require sophisticated hospital infrastructure, **enabling patient access** to therapy also in community centers, and in rural and underserved communities





## Contents

1. UV1: A universal cancer vaccine
2. Phase II pipeline & program design
3. Phase I trial results
4. Market potential and competitive edge
- 5. TET platform technology**
6. Key takeaways

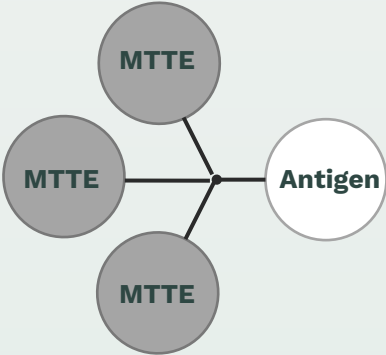


# The TET (Tetanus-Epitope Targeting) adjuvant platform technology

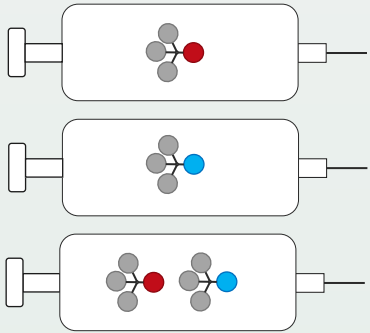
- Ultimovacs' proprietary TET technology combines the two key components of a vaccine in one molecule: The disease specific antigen and the immune response strengthening adjuvant.
- The adjuvanting effect is facilitated by sequences from tetanus toxin (Minimal Tetanus Toxin Epitope - MTTE). The MTTEs are B cell epitopes.

- An innovative technology provides the flexibility to incorporate a variety of antigens to tailor vaccines to different cancer types or infectious disease.

### Adjuvant component

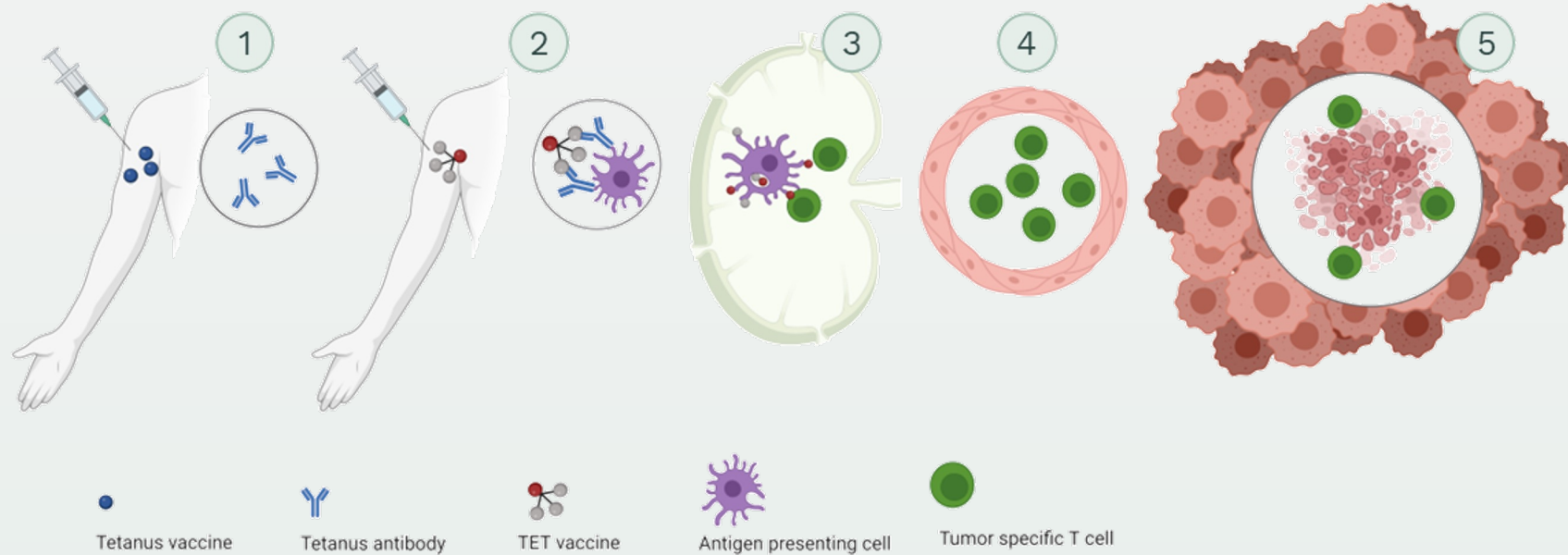


**Disease specific antigen:**  
Directs the immune response towards the target



● Fixed adjuvant component  
● ● Flexible disease specific antigen components  
Several antigens may be combined in a single administration

# TET adjuvant technology platform takes advantage of pre-existing immunity to elicit a strong and antigen specific immune response



## **TET cancer vaccine mode of action:**

### **Vaccination and immune response: Active and targeted delivery of the vaccine to antigen presenting cells**

1. Standard tetanus vaccination induces production of anti-tetanus antibodies.
2. The tetanus antibodies bind to the TET vaccine and form an immune complex, which is taken up by an antigen presenting cell. Immune complex formation is known to facilitate immunogenicity.
3. The antigen presenting cell migrates to the lymph node, and tumor specific T cells are made.

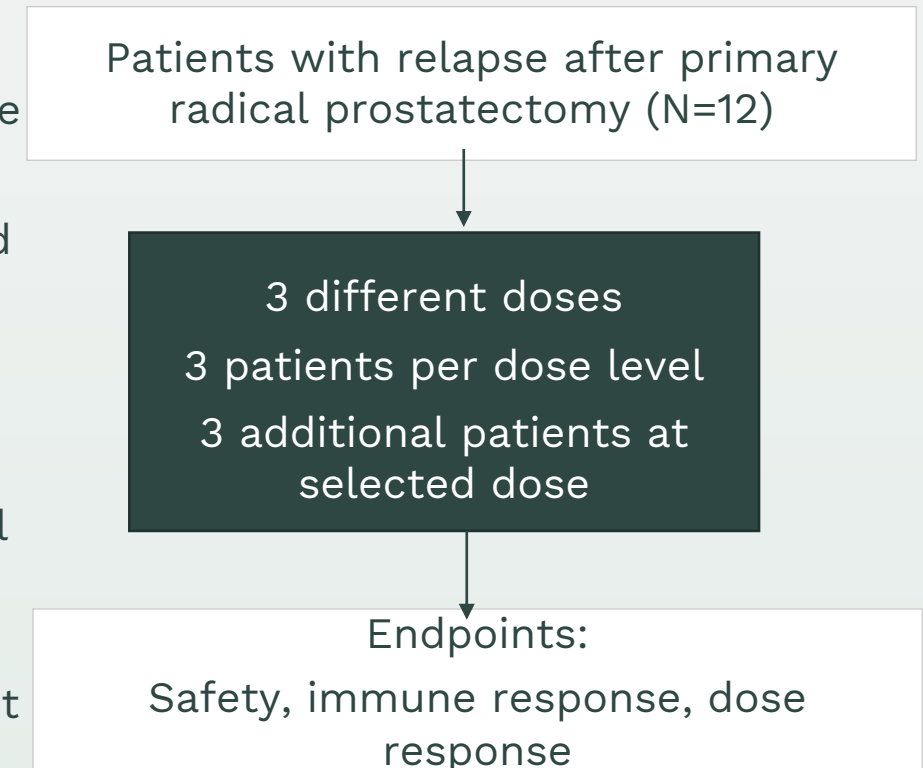
### **Killing of the tumor**

4. T cells enter blood circulation and travel to the tumor.
5. T cells infiltrate the tumor and activate a series of steps that lead to tumor cell killing.

# TENDU : First clinical evaluation of a TET vaccine

A therapeutic vaccine concept for activating specific T cells that can target and eradicate cancer cells

- **Dose-escalation, first-in-human Phase I trial: TENDU**
- The TENDU trial investigates a prostate cancer specific vaccine based on the TET technology
- Conducted at Oslo University Hospital, 12 patients participated
- Study results reported Q4 2023:
- Good safety and tolerability across all dose-cohorts;  
**meeting the primary endpoint**
- Observations of immune activation with vaccine specific T cell responses;  
**meeting the secondary endpoint**
- Advancements in preclinical research, technology development and product manufacturing, provide a valuable basis for potential expansion of Ultimovacs' pipeline





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# Ultimovacs has a highly skilled team, supported by strong, long-term shareholders, with cash runway through readout of two next Phase II trials

## Company profile

- Clinical-stage biotech, developing universal cancer vaccines
- Founded in 2011
- Listed at Euronext Oslo Stock Exchange in 2019
- 26 employees in Oslo, Norway and Uppsala, Sweden
- **Market cap<sup>1</sup>**: ~NOK 4.9 bn (~MUSD 467)
- Total cash end of Q3 2023 amounted to MNOK 300 (MUSD 28) providing an **estimated financial runway to H2 2024**

## Management



**Carlos de Sousa**  
**MD, EMBA**  
Chief Executive Officer



**Jens Bjørheim**  
**MD, PhD**  
Chief Medical Officer



**Ingunn H. Westgaard**  
**PhD**  
Head of Research



**Hans V. Eid**  
Chief Financial Officer



**Ton Berkien**  
Chief Business Officer

## Inventors



**Gustav Gaudernack**  
**Inventor, Professor Emeritus**  
Chief Scientific Officer



**Sara Mangsbo**  
**PhD, Professor**  
Chief Innovation Officer

## Shareholders<sup>2</sup>

Investor	Holding
Gjelsten Holding	18.9%
Canica	7.9%
Sundt Group <sup>3</sup>	7.7%
Watrium	5.2%
Radforsk (Biotech/oncology fund)	4.4%
Langøya Invest	4.1%
Inven2 University of Oslo TTO	3.9%
Stavanger Forvaltning	1.7%
<b>Top 20</b>	<b>64.2%</b>
<b>Other</b>	<b>35.8%</b>

## Capital markets transactions

Date	Transaction	Deal value
Oct '21	Private placement <sup>5</sup>	MNOK 270 (MUSD 28)
May '20	Private placement <sup>5</sup>	MNOK 160 (MUSD 17)
May '19	IPO	MNOK 370 (MUSD 38)

# Key takeaways: Universal cancer vaccine UV1 has potential to enhance the efficacy and durability of immunotherapies

- **Broad Phase II development program** highlights significant commercial potential, well-positioned in the emerging cancer vaccine market
- **Proof of concept:** Phase II results in malignant mesothelioma shows statistically significant and clinically meaningful improvement in overall survival in a hard-to-treat patient group
- **Good safety profile** and clear signals of clinical efficacy inducing immune response durability (>9.5 years)
- **Off-the-shelf** and easy to use
- **External validation**
  - FDA Fast Track designation in metastatic melanoma and Orphan Drug designation in metastatic melanoma and mesothelioma
  - Joint projects with large pharma companies and oncology specialist groups
- Experienced team, strong long-term shareholders, expected financial runway to H2 2024
- **Near term value inflection point: Readout of Phase II INITIUM in March 2024**



# Appendix

# Patient baseline demographics of Phase I UV1 + ipilimumab

## Malignant melanoma

### Patient characteristics

- All patients had stage IV disease
  - M1c in 50% of patients
- Elevated LDH in 50% of patients
- 33.3% of patients had received prior therapy

Patient	N (%)	
<b>Age (years)</b>	median, range	
	57 (44-74)	
<b>Sex</b>		
	female	5 (42%)
	male	7 (58%)
<b>ECOG</b>		
	0	11 (91.7%)
	1	1 (8.3%)
	≥2	0 (0%)
<b>Stage</b>		
	M1a	3 (25%)
	M1b	2 (16.7%)
	M1c	6 (50%)
	M1d	1 (8.3%)
<b>BRAF status</b>		
	Mut	3 (25%)
	wt	9 (75%)

Patient	N (%)	
<b>Liver metastases</b>		
	Yes	3 (25%)
	No	9 (75%)
<b>LDH</b>		
	above ULN	6 (50%)
	below ULN	6 (50%)
<b>Prior therapy</b>		
	Chemotherapy	2 (16.7%)
	BRAF/MEK inhibitor	2 (16.7%)
	ipilimumab	0 (0%)
<b>Prior lines of therapy</b>		
	0	8 (66.7%)
	1	4 (33.3%)
	≥2	0 (0%)



# Patient baseline demographics of Phase I UV1 + pembrolizumab

## Malignant melanoma

### Key Eligibility Criteria

- Advanced histologically confirmed malignant melanoma (stage IIIB-C, IV)
- Measurable and evaluable disease according to iRECIST
- Previously untreated and eligible for pembrolizumab (prior BRAF and MEK inhibitors permitted)
- ECOG 0-1
- Active brain metastases, and uveal or ocular melanoma not permitted

Characteristic	N=30
<b>Median age</b> (range) - years	70.5 (30-87)
<b>Male sex</b> - no. (%)	21 (70)
<b>ECOG performance status</b> - no. (%)	
0	19 (63)
1	11 (37)
<b>Elevated baseline LDH</b> - no. (%) *	9 (31)
<b>Stage</b> (8 <sup>th</sup> edition AJCC) - no. (%)	
IIIB	2 (7)
IIIC	9 (30)
IV	19 (63)
M1a	5 (17)
M1b	5 (17)
M1c	8 (27)
M1d	1 (3)

Characteristic	N=30
<b>Liver metastasis</b> - no. (%)	4 (13)
<b>BRAF V600E status</b> - no. (%) †	
Mutated	10 (37)
<b>PD-L1 status</b> - no. (%) ¶	
Positive (≥1%)	8 (36)
<b>Tumor mutation burden</b> - no. (%) £	
High (≥20 mutations/Mb)	3 (18)
Intermediate (6-19 mut/Mb)	6 (35)
Low (1-5 mutations/Mb)	8 (47)

# Favorable safety profile of Phase I UV1 + pembrolizumab

## Malignant melanoma

### Safety of UV1 vaccination

- Safety profile of UV1 in combination with pembrolizumab comparable to that of pembrolizumab alone
- Grade 3 adverse events in 20% of patients – **no grade 4 or 5 events**
- Adverse event type and frequency similar to that of pembrolizumab alone
- Mild grade 1-2 injection site reactions attributable to UV1

Adverse Event	N=30	
	Any grade	Grade 3
<b>Related to treatment*</b>		
Any	21 (70.0)	6 (20.0)
Occurring in more than one patient or grade $\geq 3$		
Fatigue	10 (33.3)	0
Injection site reaction	6 (20.0)	0
Hypothyroidism	6 (20.0)	0
Colitis	5 (16.7)	2 (6.7)
Diarrhea	5 (16.7)	0
Pruritus	4 (13.3)	0
Hyperthyroidism	4 (13.3)	1 (3.3)
Rash	3 (10.0)	0
Arthritis	2 (6.7)	2 (6.7)
Dyspnoea	2 (6.7)	0
Chorioretinitis	1 (3.3)	1 (3.3)
Diabetes mellitus	1 (3.3)	1 (3.3)

Historical reference study: KEYNOTE-006 (Robert C, 2019)

**Any treatment-related adverse event:** 79%

**Grade 3-5 adverse events:** 18%

# Fast track and orphan drug designation confirms our confidence in the therapeutic potential of UV1










## Ultimovacs is granted Fast Track designation from the FDA

- UV1 as add-on therapy to pembrolizumab for the treatment of malignant melanoma
- UV1 as add-on therapy to ipilimumab for the treatment of malignant melanoma
- Fast track is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need  
The purpose is to get important new drugs to the patient earlier

## Ultimovacs is granted Orphan Drug designation from the FDA

- UV1 in the treatment of patients with malignant melanoma
- UV1 in the treatment of patients with mesothelioma
- A status given to certain drugs which show promise in the treatment, prevention, or diagnosis of orphan diseases; a rare disease or condition that affects fewer than 200,000 people with unmet medical needs in the US. The intention of the program is to support and advance the development and evaluation of new treatments.

# Experienced Board of Directors

 <p><b>Jonas Einarsson</b> Chairman of the board</p>	<ul style="list-style-type: none"> <li>CEO of the Norwegian Radium Hospital Research Foundation</li> <li>Board member of several biotech companies</li> <li>One of the initiators behind the Norwegian Center of Expertise, Oslo Cancer Cluster</li> </ul>	 <p><b>Henrik Schüssler</b> Board member</p>	<ul style="list-style-type: none"> <li>CEO and board member of Gjelsten Holding AS</li> <li>Previously CFO and CEO of Norway Seafood</li> <li>Accounting/consulting experience from Ernst &amp; Young</li> </ul>	 <p><b>Haakon Stenrød</b> Board member</p>	<ul style="list-style-type: none"> <li>Senior Investment Manager at Watrium</li> <li>Previously 12 years in the Investment Banking at ABG Sundal Collier, focusing on M&amp;A, restructurings and capital markets advisory</li> <li>Board member of DF Capital, a UK challenger bank listed on AIM London</li> </ul>
 <p><b>Leiv Askvig</b> Board member</p>	<ul style="list-style-type: none"> <li>Investment Advisor at Sundt AS, a Norwegian family owned investment company</li> <li>Board member of Padox AB, Eiendomsspar, Oncoinvent AS and Civita</li> <li>Previously Chairman of the Board of Oslo Stock Exchange and CEO of Sundal Collier &amp; Co</li> </ul>	 <p><b>Kari Grønås</b> Board member</p>	<ul style="list-style-type: none"> <li>Extensive experience in drug development and commercialization within the pharmaceutical industry of new breakthrough products securing regulatory approvals, i.e. Xofigo, Hexvix</li> <li>Board positions in Spago Nanomedical AB, SoftOx AS and The Norwegian Lung Cancer Society</li> </ul>		
 <p><b>Ketil Fjerdings</b> Board member</p>	<ul style="list-style-type: none"> <li>25+ years experience from board and management positions in different companies and industries</li> <li>Ultimovacs' Chairman of the board from '11-'17</li> </ul>	 <p><b>Eva S. Dugstad</b> Board member</p>	<ul style="list-style-type: none"> <li>Manager for Business and Community Relations at Faculty of Mathematics and Natural Sciences, University of Oslo</li> <li>Previously Director for Business Development at Radforsk and President and EVP at the Institute for Energy Technology (IFE)</li> <li>Has been involved in various boards in both public and private sector and in several public expert panels</li> </ul>		

# Management Team with proven execution capabilities



**Carlos de Sousa**

MD, EMBA  
CEO



**Jens Bjørheim**

MD, PhD  
CMO



**Ingunn H. Westgaard**

PhD  
Head of Research



**Hans Vassgård Eid**

MSc Business  
CFO



**Gudrun Trøite**

PhD  
Head of Project  
Coordination



**Audun Tornes**

MSc  
CTO



**Orla Mc Callion**

PhD  
Head of Regulatory &  
QA



**Øivind Foss**

Dr.Scient  
Head of Clinical  
Operations



**Ton Berkien**

BA Econ  
CBO



**Anne Worsøe**

MSc Business  
Head of Investor  
Relations



[ir@ultimovacs.com](mailto:ir@ultimovacs.com)